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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/486,037	02/18/2000	SYLVAIN ORENGA	105454	7665

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EXAMINER	
NAVARRO, ALBERT MARK	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 12/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/486,037	ORENGA, SYLVAIN	
	Examiner	Art Unit	
	Mark Navarro	1645	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 26 November 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires *4* months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☒ The proposed amendment(s) will not be entered because:

   (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: *See attached*.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☐ The a)☐ affidavit, b)☐ exhibit, or c)☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☐ For purposes of Appeal, the proposed amendment(s) a)☒ will not be entered or b)☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: *20-28*.

   Claim(s) objected to: _____.

   Claim(s) rejected: *1,2,4-12,19 and 29-31*.

   Claim(s) withdrawn from consideration: _____.

8. ☐ The drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. ☐ Other: _____

ADVISORY ACTION

Applicant's amendment after final filed November 26, 2003 has been received but not entered. Consequently, claims 1-2, 4-12 and 19-31 remain pending in the instant application.

It is noted that Applicants assert that claim 1 has been merely amended to incorporate the features of claim 5, which was indicated in the October 23, 2002 Office Action to be free of the prior art art and is not rejected over prior art in the present Office Action. However, Applicants amendment involves the "deletion" of a limitation from claim 1, "wherein said compound is not formamide." Removing claim limitations involve new searches for the claimed invention and new considereations under 35 USC 112. Clearly, deletion of this limitation requires new considerations. The Examiner cannot add any new grounds of rejection at this point, and the only way to determine if the limitation can be removed and still remain free of the prior art is to conduct a new search. Accordingly, this amendment has not been entered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

1. The rejection of claims 1-4 and 6-8 under 35 U.S.C. 102(b) as being anticipated by Kaneko et al is maintained.

Applicants are asserting that claim 1 has been amended to recite that the compound that selectively inhibits the hexosaminidase activity of C. tropicalis is "not formamide." Applicants assert that Kaneko does not disclose such a medium.

Applicants arguments have been fully considered but are not found to be fully persuasive.

Applicants have amended claim 1 to recite that the compound that selectively inhibits the hexosaminidase activity of C. tropicalis is "not formamide." However, this limitation is still not sufficient to overcome the disclosure of Kaneko et al. As set forth in the office action mailed October 23, 2002 Kaneko disclose of a composition comprising 5-bromo-4-chloro-3-indolyl-β-D-glucuronic acid and dimethyl formamide. Those of ordinary skill in the art would readily appreciate that dimethyl formamide has a distinct structure from that of formamide. Consequently, the amendment to recite "not formamide" does not exclude the compound "dimethyl formamide."

The claims are drawn to culture medium for the specific identification and/or differentiation of *Candida albicans* and *Candida tropicalis* yeast, comprising a chromogenic or fluorigenic substrate, which can be hydrolyzed by an enzyme of the hexosaminidase family,

wherein the medium also comprises at least one compound that selectively inhibits the hexosaminidase activity of *C. tropicalis*, wherein said compound is not formamide.

Kaneko et al (U.S. Patent Number 5,272,072) disclose of a composition comprising 5-bromo-4-chloro-3-indolyl-β-D-glucuronic acid and dimethyl formamide. (See column 9).

In view that 5-bromo-4-chloro-3-indolyl-β-D-glucuronic is a chromogenic substrate that can be hydrolyzed by an enzyme of the hexosaminidase family and that dimethyl formamide selectively inhibits the hexosaminidase activity of *C. tropicalis*, the disclosure of Kaneko et al is deemed to anticipate the claimed invention.

It is noted that Kaneko et al do not disclose culturing Candida with the composition, however culturing Candida with the composition is merely an intended use of the composition and therefore carries no patentable weight.

For reasons of record in Paper Number 14, as well as the reasons set forth above, this rejection is maintained.

2. The rejection of claims 19 under 35 U.S.C. 102(e) as being anticipated by Wong-Madden et al is maintained.

Applicants are asserting that Wong-Madden do not teach a microbiological analysis process for selectively identifying and/or differentiating the C. albican and/or C. tropicalis yeasts,

characterized in that the sample to be analyzed is placed directly in contact with the medium of claim 1.

Applicants arguments have been fully considered but are not found to be fully persuasive.

Applicants attention is directed to claim 19, which recites "microbiological analysis process for selectively identifying the C. albicans and/or C. tropicalis yeast and/or for differentiating C. albicans and C. tropicalis yeasts, characterized in that the sample to be analyzed is placed directly in contact with at least one identification medium according to claim 1."

Applicants have not traversed that Wong-Madden teach the composition of claim 1. Applicants have only asserted that Wong-Madden do not teach the microbiological analysis part. However, Wong-Madden et al have taught the identical composition as claimed in claim 1, and further inoculated a sample into the medium. Consequently, each and every limitation has been addressed by Wong-Madden et al. The claim does not require a step of identifying a certain species of Candida, allowing colors to appear in the medium, or anything else to differentiate from what Wong-Madden et al already preformed. "Generally, the preamble does not limit the claims... the preamble may be limiting 'when the claim drafter chooses to use both the preamble and the body to define the subject matter of the claimed invention.'" Allen Eng'g Corp. v. Bartell Indus., v. Darragh Co., 63 USPQ2d 1769, 1774 (Fed. Cir. 2002). "A statement of intended use or purpose usually will not limit the scope of the claim since such statements merely define the context in which the invention operates. However, preamble language may limit the claim if it

recites not merely a context in which the invention may be used, but give meaning to the limitations recited in the body of the claim." DeGeorge v. Bernier, 226 USPQ 758, 761 n.3 (Fed. Cir. 1985).

In view that the body of the claim merely recites placing a sample in the culture medium of claim 1, and that Wong-Madden et al placed a sample in a medium identical to the medium recited in claim 1, the disclosure of Wong-Madden et al is deemed to anticipate the claimed invention.

The claims are drawn to microbiological analysis process for selectively identifying the C. albicans and/or C. tropicalis yeast and/or for differentiating C. albicans and C. tropicalis yeasts, characterized in that the sample to be analyzed is placed directly in contact with at least one identification medium according to claim 1.

Wong-Madden (U.S. Publication 2002/0137176) disclose of multiple chromogenically labeled substrates in a composition. (See pages 6-9).

In view that Wong-Madden disclose of multiple chromogenically labeled substrates that can be hydrolyzed by an enzyme from the hexosaminidase family, and chromogenically labeled substrates that can be hydrolyzed by an enzyme from the glucosidase family, and further placing a sample in the medium, the disclosure of Wong-Madden et al is deemed to anticipate the claimed invention.

Claim Rejections - 35 USC § 112

3. Claims 1-2, 4-12, 19 and 29-31 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 1 has been amended to newly recite that the at least one compound that selectively inhibits the hexosaminidase activity of C. tropicalis, "wherein said compound is not formamide." However, Applicants have not pointed to support for claiming an entire genus of compounds that inhibit hexosaminidase while excluding formamide from this list. Furthermore, Applicants claimed composition clearly encompasses formamide. (See claims 9 and 31). Consequently, the newly cited limitation of excluding formamide from the compounds which inhibit the hexosaminidase activity of C. tropicalis must have clear support within the originally filed specification. Applicant is required to demonstrate this support (page and line number) or cancel the newly added material.

Claims 20-28 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro, whose telephone number is (703) 306-3225. The examiner can be reached on Monday - Thursday from 8:00 AM - 6:00 PM. The examiner can be reached on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Lynette Smith can be reached at (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Group 1645 by facsimile transmission. Papers should by faxed to Group 1645 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the official Gazette 1096 OG 30 (November 15, 1989). The CMI Fax Center number is (703) 308-4242.

Mark Navarro

Primary Examiner

December 23, 2003